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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,532	03/20/2001	David Allen Schul	8003	2563

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EXAMINER

JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 04/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/812,532

Applicant(s)

SCHUL ET AL.

Examiner

Shaojia A. Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57-63 and 65-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 57-63 and 65-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 10, 2005 has been entered.

This Office Action is a response to Applicant's request for continued examination (RCE) filed January 10, 2005, and amendment and response to the Final Office Action (mailed February 4, 2004), filed January 10, 2005 wherein claims 57-63 and 65-69 have been amended. Claims 1-56 and 64 are cancelled previously.

Currently, claims 57-63 and 65-69 are pending in this application.

Claims 57-63 and 65-69 are examined on the merits herein.

Note that this application claims benefit of 60/192,412, filed 03/27/2000.

Applicant's amendment filed January 10, 2005 with respect to the rejection of claims 57-63 and 65-69 made under 35 U.S.C. 112 first paragraph for containing new subject matter which was not described in the original specification and claims, i.e., "more than 10% of a sterol fatty ester composition", of record stated in the Office Action dated February 4, 2004 have been fully considered and found persuasive to remove the

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rejection since the claims have been amended to recite the range of 10-30%. Therefore, the said rejection is withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 57-63 and 65-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson (3,751,569, of record) and Miettinen et al. (5,502,045, of record) and Wester et al. (WO 99/56558, of record).

Erickson discloses a clear cooking and salad oil comprising 0.5-10% by weight of the composition of a sterol fatty acid ester, which comprises 100% the particular monounsaturated fatty acid moiety, oleic acid moiety (oleic acid is a known monounsaturated fatty acid, see its chemical structure provided in the Merck Index page 6967). Note that the range of a sterol fatty acid ester in Erickson touches or overlaps with the instant claimed range, 10-30%.

The sterol fatty acid ester employed in the composition therein is β -sitosteryl oleate or stigmasteryl oleate (see particularly Table I at col. 3-4 and Table II at col.5). See also col.1 lines 14-18 and 59-65; col.3 lines 1-30. Thus, the sterol oleic acid esters, β -sitosteryl oleate or stigmasteryl oleate, in the composition therein comprise about

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100% oleic acid moiety, which reads on more than 50% monounsaturated fatty acid moiety recited in the claim 57.

Miettinen et al. disclose that sterol fatty acid esters such as fatty acid esters of β -sitosterol and β -sitostanol are useful in compositions for reducing serum cholesterol level. See abstract, col.1 lines 10-15, col.3 lines 45-50, col.4 lines 19-24 and 64-65. The sterol fatty acid ester compositions therein can be added to oils (see particularly in Example 2-4 at col.5-6), such as at 3, 6, and 13 % by weight to rapeseed oil (Example 2-3 at col.5-6), and at about 10-20% weight to margarine (see Example 2-5 at col.5-6), and especially the rapeseed oil with the ester mixture added remained clear at room temperature (known at about 60-70°F) (see col.6 lines 23-25). Miettinen et al. also disclose that the sterol fatty acid esters therein employed in the compositions are prepared by, for example, β -sitostanol and rapeseed oil fatty acid methyl ester (i.e., interesterifying rapeseed oil fatty acid methyl ester with β -sitostanol to make β -sitostanol rapeseed oil fatty acid esters, see particularly at Example 1 at col.5 lines 34-47). The conversion rate of esterification therein was achieved to 98% (see col.5 lines 45-46). Thus, one of ordinary skill in the art would clearly recognize that the unesterified sterol level therein could be 2%, within the instant claim, less than 3, 5, or 10%.

Wester et al. discloses that fatty acid esters of phytosterols and phytostanols (such as sitosterol, campesterol and stigmasterol) are known to be useful in compositions for reducing serum cholesterol level. See abstract, page 1-3. Wester et al. also disclose that these sterol fatty acid esters compositions can be added to cooking oils and salads oils for the same purpose to reduce serum cholesterol level. See page 4

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lines 9-31. Wester et al. also disclose that rapeseed oil employed for making stanol fatty acid esters is known to contain a low content of saturated fatty acids and a high content of unsaturated fatty acids (mainly monounsaturated) (see particularly at page 5 lines 14-17). Wester et al. further disclose that particular sterol fatty acid esters compositions comprise less than 5 or 7% saturated fatty acids (SFAs) (see particularly page 5 lines 8-9, and claims 1-2) and more than 50% PUFA as fatty acid moieties (see particularly page 5 lines 6-7 and claims 1-7).

Erickson does not expressly disclose a clear cooking and salad oil comprising more than 10% by weight of the composition of a sterol fatty acid ester. Miettinen et al. and Wester et al. do not expressly disclose particular sterol fatty acid esters compositions herein comprising more than 50%, about 55-80%, or about 60-70% of fatty acid moieties which are monounsaturated fatty acids (MUFAs) and less 50% polyunsaturated fatty acids (PUFA) moieties.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ more than 10% by weight of the composition of a sterol fatty acid ester, and to employ more than 50%, about 55-80%, or about 60-70% of monounsaturated fatty acid (MUFA) moieties and less 50% PUFA moieties in particular sterol fatty acid esters compositions herein.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ more than 10% by weight of the composition of a sterol fatty acid ester since more than 10% by weight of the composition of a sterol fatty acid ester to be added in food products such as vegetable oils has been disclosed by

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Miettinen et al. Moreover, the range of a sterol fatty acid ester in Erickson, 0.5-10%, touches or overlaps with the instant claimed range, 10-30%. The claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 2144.05 [R-1].

One having ordinary skill in the art at the time the invention was made would have been motivated to employ more than 50%, about 55-80%, or about 60-70% of monounsaturated fatty acid (MUFA) moieties and less 50% PUFA moieties in particular sterol fatty acid esters compositions herein since the sterol rapeseed oil fatty acid esters compositions at about 10% by weight are known to be added into the edible oil according to Miettinen et al. Moreover, rapeseed oil is known to contain a low content of saturated fatty acids and a high content of unsaturated fatty acids (including monounsaturated fatty acids and polyunsaturated fatty acids) but mainly monounsaturated fatty acids according to Wester et al. Further, the sterol oleic acid esters, β -sitosteryl oleate or stigmasteryl oleate, in the composition therein comprise about 100% oleic acid moiety is known according to Erickson.

Thus, one of ordinary skill in the art would have reasonably interpreted that mainly monounsaturated fatty acids in a high content of unsaturated fatty acids, might be more than 50%, about 55-80%, or about 60-70% of monounsaturated fatty acids and less than 50% of polyunsaturated fatty acids in rapeseed oil. Hence, based on the teachings of Wester et al., the sterol rapeseed oil fatty acid esters compositions of

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Miettinen et al. would have reasonably been considered to comprise more than 50%, about 55-80%, or about 60-70% of monounsaturated fatty acids and less than 50% of polyunsaturated fatty acids.

Further, both Miettinen et al. and Wester et al. teach the same therapeutic usefulness of sterol fatty acid ester compositions for reducing serum cholesterol level and these sterol fatty acid esters compositions can be added to cooking oils and/or salads oils for the same therapeutic purpose. Therefore, one of ordinary skill in the art would have found it obvious to employ sterol rapeseed oil fatty acid esters compositions comprising more than 50%, about 55-80%, or about 60-70% of monounsaturated fatty acid moieties and less than 50% PUFA moieties in an edible oil.

Therefore, the combined teachings of Erickson, Miettinen et al. and Wester et al. have clearly provided the motivation of the instant claimed sterol fatty acid ester compositions.

Furthermore, the optimization of known amounts of active agents, e.g., monounsaturated fatty acids, polyunsaturated fatty acids, and saturated fatty acids in a known composition to achieve desirable physical properties is considered well within the skill of artisan, involving merely routine skill in the art. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Response to Argument

Applicant's arguments filed January 10, 2005 with respect to the rejection made under 35 U.S.C. 103(a) as being unpatentable over the same references of record in the previous Office Action February 4, 2004 have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as further discussed below.

These remarks are believed to be adequately addressed by the obvious rejection presented above.

Additionally, In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, as discussed above, the combined teachings of Erickson, Miettinen et al. and Wester et al. have clearly provided the motivation of the instant claimed sterol fatty acid ester compositions.

Applicant's working Examples of the specification at pages 23-32 herein have been fully considered but are not deemed persuasive as to the nonobviousness and/or unexpected results of the claimed invention over the prior art. Examples provide no clear and convincing evidence of nonobviousness or unexpected results over the cited

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prior art since there is no side-by-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art. Moreover, it is unclear that the compositions in Examples herein are within the instant claims, e.g., the particular percentage of MUFA and the particular percentage of a sterol fatty acid ester. Thus, the evidence in the examples does not clearly demonstrate being commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the ingredients in the claimed composition. See MPEP § 716.02(d).

It is noted that arguments of counsel cannot take the place of factually supported objective evidence. See, e.g., *In re Huang*, 100 F.3d 135, 139-40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996); *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984).

Therefore, the evidence presented in specification herein is not seen to be clear and convincing in support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a).

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



S. Anna Jiang, Ph.D.
Primary Examiner
Art Unit 1617
March 24, 2005